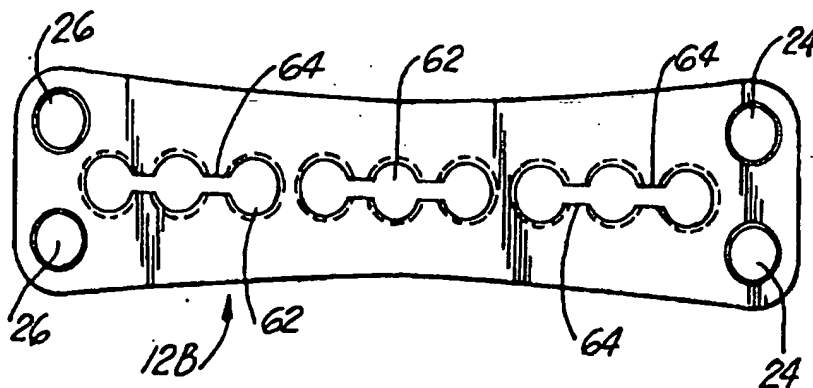


(51) International Patent Classification 6 : <b>A61B 17/70</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/22306</b> (43) International Publication Date: 26 June 1997 (26.06.97)
(21) International Application Number: PCT/US96/20707 (22) International Filing Date: 20 December 1996 (20.12.96) (30) Priority Data: 08/575,601                      20 December 1995 (20.12.95)      US (71) Applicant: SMITH & NEPHEW INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US). (72) Inventors: FOLEY, Kevin, T.; Suite 600, 930 Madison Avenue, Memphis, TN 38103-3440 (US). KLARA, Peter, M.; Suite 1100, 880 Kempsville Road, Norfolk, VA 23502 (US). MAXWELL, Keith; Suite 200, 41 Oakland Avenue, Asheville, NC 28801 (US). MIDDLETON, Lance; 7350 Royce Cove, Memphis, TN 38125 (US). MORRISON, Matthew, M.; 7882 Meadow Vale Drive, Memphis, TN 38125-3144 (US). (74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, P.C., 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published <i>With international search report.</i>

(54) Title: OSTEOSYNTHESIS APPARATUS



## (57) Abstract

A bone fixation apparatus (10) is disclosed which includes an elongated plate member (12) with at least two pairs of circular openings (24, 26) and a series of circular openings (62) positioned along the plate member (12). The circular openings each form a cavity (30) with walls (31) extending between the upper and lower plate member surfaces (16, 18), the cavities having smaller diameter portions (32) at the plate member surfaces (16, 18) and a larger diameter portion (34) therebetween. The cavities are configured in the shape of two inverted cones (31a, 31b) with matching base circles (31c) for allowing angulation of an implanted bone screw (14). A plurality of bone screws (14) are provided, each having a threaded first end portion (36) and an ellipsoid-shaped enlarged second end portion (40). A locking member (48) is also provided which connects to the second end portion (40) of each bone screw (14) for expanding the second end portion (40) so as to grip the cavity wall (31) of the plate member (12).

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

## **OSTEOSYNTHESIS APPARATUS**

5       The present invention relates to an improved bone or spinal fixation apparatus in the form of an elongated plate member and a locking bone screw. The apparatus has particular utility in anterior cervical spine fixation by providing a plate that allows for angulation of the bone screws and a locking bone screw that secures the bone  
10 screws into the plate member at a selected angle corresponding to a thick region of the bone mass.

There are a number of surgical procedures which require fixation of portions of the spine with respect to one another.  
15 Typically, bone screws are employed in the fixation of the spine where the implantation of the bone screws is a surgical procedure in which one or more surgical openings are formed in adjacent portions of the spine and threaded bone screws are implanted into the surgical openings. Connective structures such as rods or plates  
20 extend between the various spine members and are connected to the spine members by the implanted bone screws.

In the treatment of spinal disorders and spinal fractures, both a posterior and an anterior approach is used. The use of plating  
25 systems for posterior internal fixation of the spine is well known. Additionally, several plating systems have been developed for anterior internal fixation of the spine. For example, the Syracuse I-plate provides a number of differently-sized I-shaped plates which are engaged across the vertebrae. A contoured anterior spinal  
30 fixation plate is known which includes a number of screw openings through the contoured plate. The number of openings simply provide different locations for engaging a bone screw to the vertebrae, and does not allow for angulation of the bone screws. A further problem with the application of spinal fixation systems is the

placement of such a system in the cervical region of the spine where correct anatomical fit and lack of bone mass presents a problem.

Even with these known posterior and anterior plate fixation systems, there remains a need for a plate and screw system that allows for variation in screw placement along the longitudinal axis of the plate as well as providing for angulation in both the medial-lateral or transverse plane and the cephalad-caudal or longitudinal plane. There is also a need for a fixation system that provides a locking bone screw mechanism for securely fastening the bone screw in a selected angled position within the plate particularly for locking a bone screw in the center portion of the plate. There is further a need for a fixation plate that is curved to fit the contours of the vertebrae and is also somewhat bendable during implantation but rigid enough to allow fusion to take place after implantation.

It is thus an object of the present invention to provide a bone fixation system that offers a strong and stable construct for maximum fusion augmentation of any bone structure and yet is versatile enough for a variety of bone configurations and is easy to use.

According to the present invention a bone fixation apparatus comprises

25

- a) An elongated plate member having a longitudinal plane, a longitudinal axis, upper and lower surfaces, opposed longitudinal side edges, at least two pairs of circular openings and a plurality of circular openings positioned along the longitudinal plane of the plate member, said circular openings each having a central vertical axis;

30

b) said circular openings each forming a cavity with walls extending between the upper and lower plate member surfaces with at least a plurality of said cavities having smaller diameter portion therebetween, for allowing transverse and longitudinal angulation of an implanted bone screw,

c) a plurality of bone screws each having a threaded first end portion adapted for implantation into a patient's bone mass and an enlarged second end portion; and

d) a locking member that connects to the second end portion of each bone screw for expanding the second end portion so as to form an interference fit between the cavity wall of the plate member and said enlarged second end portion of the bone screw, thereby to lock each bone screw into a selected position within said circular openings of the plate member.

15

The present invention provides an apparatus that can be used on any segment of the spine and in particular can be made small enough for anterior cervical spine applications.

20 The cavities are preferably configured in the shape of two inverted cones with matching base circles for allowing transverse and longitudinal angulation of an implanted bone screw.

25 The bone fixation apparatus further includes a plurality of bone screws each having a threaded end for implanting into a patient's bone mass and an ellipsoid shape enlarged second end portion. The second end portion has a locking member for expanding the second end portion so as to grip the cavity wall of the plate and for locking each bone screw into a selected position within the circular openings of the plate.

30

According to the invention we also provide a bone fixation apparatus,

- a) having a longitudinal plane, a longitudinal axis, upper  
5 and lowe surfaces, opposed longitudinal side edges, at least two  
pairs of circular openings and a plurality of generally circular  
openings positioned along the longitudinal plane of the plate  
member, said circular openings each having a central vertical axis;
- b) said circular openings each forming a cavity with walls  
10 extending between the upper and lower plate member surfaces with  
at least a plurality of said cavities having smaller diameter portions  
at the plate member upper and lower surfaces and a larger  
diameter portion therebetween, for allowing transverse and  
longitudinal angulation of an implanted bone screw;
- c) said plate member having a first end, a second end  
15 and a center portion wherein the width of the plate is smaller in the  
region of the center portion than at the first and second ends; and
- d) said one pair of circular openings being positioned at  
the first end of the plate member and the second pair of circular  
20 openings being positioned at the second end of the plate member.

For a further understanding of the nature and objects of the  
present invention, reference should be made to the following  
detailed description taken in conjunction with the accompanying  
25 drawings, in which like parts are given like reference numbers,  
wherein:

Figure 1 is an anterior view of an embodiment of the  
apparatus of the present invention illustrating its placement on the  
anterior cervical bone tissue;

30 Figure 2 is a plan view of an embodiment of the apparatus of  
the present invention illustrating a plate member;

Figure 3 is a side view of the plate shown in Figure 2;

Figure 3A is a side view of an alternate embodiment of the plate shown in Fig. 2;

Figure 4 is a sectional view of a portion of the plate shown at lines 4-4 of Figure 2;

5        Figure 5 is a sectional view of a portion of the plate shown at lines 5-5 of Figure 2;

Figure 6 is a partial sectional view of the plate shown at lines 6-6 of Figure 2;

10       Figure 7 is a front view of an embodiment of the apparatus of the present invention illustrating a locking bone screw;

Figure 8 is a front view of an embodiment of the apparatus of the present invention illustrating a locking member that connects to the bone screw of Figure 7;

15       Figure 9 is a top view of the bone screw of Figure 7 with the locking member of Figure 8 in its locked position;

Figure 10 is a fragmentary sectional view of an embodiment of the apparatus of the present invention illustrating the bone screw of Figure 7 placed in an angled position;

20       Figure 11 is a fragmentary sectional view of an embodiment of the apparatus of the present invention illustrating a longitudinal range of angulation of an implanted bone screw;

Figure 12 is a fragmentary sectional view of an embodiment of the apparatus of the present invention illustrating a transverse range of angulation of an implanted bone screw;

25       Figure 13 is a plan view of another embodiment of the apparatus of the present invention illustrating a plate member;

Figure 14 is a plan view of another embodiment of the apparatus of the present invention illustrating a plate member;

30       Figure 15 is a plan view of an alternate configuration of the openings of the plate member of Fig. 14; and

Figure 16 is a plan view of an alternate configuration of the openings of the plate member of Fig. 14.

FIGS. 1 show the various embodiments of the bone fixation apparatus of the present invention, designated generally by the numeral 10, implanted on the anterior side of cervical vertebrae V of a human patient. The bone fixation apparatus 10 includes a plate member 12 and locking bone screws 14. The plate 12, as shown in FIG. 2, is an elongated plate member 12 having a longitudinal axis LA, a longitudinal plane LP and upper and lower surfaces 16, 18. The plate member 12 has apposed longitudinal side edges 20, 22, first and second ends 23, 25 and a center portion 21. The center portion 21 preferably has a generally smaller width in relation to a larger width at the first and second ends 23, 25. Plate member 12 has a transverse plane TP (FIG. 2) and the plate member 12 can be curved along the transverse plane TP. If curved, the radius of the transverse curve cross-section is between about 22.0 to 77.0 millimeters and is illustrated in FIGS. 4 and 5. As shown in FIG. 3, the plate member 12 can be generally flat along the longitudinal plane LP or the plate member 12 can be curved along the longitudinal plane as illustrated in FIG. 3A. The longitudinal curve can have an arc angle of between about 6° to 40°. The curve in both the transverse plane and the longitudinal plane will allow the plate member 12 to achieve a better fit in on the selective vertebrae particularly in the anterior cervical portion of the spinal column.

The plate member 12 includes a pair of circular openings 24 positioned at its first end 23 and a second pair of circular openings 26 positioned at its second end 25. A series of openings, such as at least one elongated slot 28 is positioned along the longitudinal plane LP of the plate member 12. The series of openings can be positioned along the longitudinal axis LA or offset from the longitudinal axis LA. In one embodiment three elongated slots 28 are positioned along the longitudinal axis LA of the plate member



12. The circular openings 24, 26 and elongated slots 28 have a central vertical axis CA, as illustrated in FIGS. 4 and 5. In an alternate embodiment, more than two pairs of circular openings can be placed on the ends of the plate member 12.

5

The openings 24, 26 and the elongated slots 28 of the plate member 12 each form a cavity 30 with angled walls 31 extending between the upper and lower plate member surfaces 16, 18. The angled walls 31 form two inverted cones 31a, 31b with matching  
 10 base circles 31c. The cavities 30 have smaller diameter wall portions 32 at the upper and lower plate surfaces 16, 18 and a central larger diameter wall portion 34 therebetween. The diameter of the wall portions 32 are larger at the upper surface 16 than the diameter of the wall portions 32 at the lower plate surface 18, but  
 15 the diameter of the wall portions 34 is always larger than that at both the upper and lower surfaces 16, 18. The slightly smaller diameter of the wall portions 32 at the lower surface 18 of the plate member 12 keeps the bone screw 14 from slipping through the cavities 30 prior to insertion of the locking member 48 into the central bore 42  
 20 of the bone screw 14. The angulation of the wall surfaces 31 or the inverted cones 31a, 31b, between the upper and lower plate surfaces 16, 18, is generally about between 110° to 160°. The cavities 30 of the openings 24, 26 and slots 28 are shaped to allow for a transverse angulation of each of the bone screws 14 generally  
 25 up to about 35° in both directions from the central vertical axis CA of the openings 24, 26 and slots 28 when each of the bone screws 14 is inserted into the openings 24, 26 and slots 28 (FIG. 12). The cavities 30 of the openings 24, 26 are shaped to allow for a longitudinal angulation of each of the bone screws 14 generally up  
 30 to about 35° in both directions from the central vertical axis of the openings 24, 26 when each of the bone screws 14 is inserted into each of the openings 24, 26 (FIG. 12). The cavities 30 of the slots

28 are shaped to allow for a longitudinal angulation of each of the bone screws 14 of generally between 0° to 130° in both directions from the central vertical axis of the slots 28 when each of the bone screws 14 is inserted into each of the slots 28 (FIG. 11). The openings 24, 26 and slots 28 have a beveled surface 15 on the upper and lower plate surfaces 16, 18 as illustrated in FIGS. 4-6.

The geometry of the plate member 12, plus the load factors of the openings 24, 26 and slots 28, allow the plate member 12 to be somewhat bendable during implantation while still maintaining the rigidity needed for adequate fixation and immobilization of the vertebrae. Additionally, the ability of plate member 12 to have either a transverse or longitudinal curve allows for a closer fit to the contours of the vertebrae.

FIG. 13 illustrates plate member 12A, an alternate embodiment of plate member 12, having a plurality of openings 60 positioned along the longitudinal plane LP of the plate member 12A. The provision of a plurality of circular openings along the longitudinal plane of the plate member offers the flexibility of choosing one of a number of different positions along the length of the plate in which to secure a bone screw and thus the screw may be placed in the part of the bony mass to be secured which appears most advantageous to the surgeon. Although the provision of slots along the longitudinal plane of the plate offers a great deal of choice in the longitudinal placement of the screws, circular openings may provide a more secure fixation between the screw head and the plate because the area of contact between the screw head and the plate is greater. Each circular opening 60 is spaced at least about 1.8 to 2.0 millimeters apart from each other. The plurality of openings 60 can include any number of individual openings and in a preferred embodiment up to about sixteen (16) individual openings

60. Each of the plurality of openings 60 has the same configuration as the openings 24, 26. All other aspects of plate member 12A are the same as plate member 12.

5           FIGS. 14-16 illustrates another alternate embodiment plate member 12, plate member 12B, which has a plurality of circular openings 62 positioned along the longitudinal plane LP of the plate member 12B with each circular opening 62a being connected to a next circular opening 62b by a narrow slot 64. The narrow slot 64  
10 has a width that is equal to about between  $1/3$  to  $1/2$  the diameter of each circular opening 62 and a length that is between about 1.4 to 2.00 millimeters. The width of the narrow slot 64 is smaller than the diameter of any bone screw that would be inserted into the circular openings 62 and does not allow for the sliding of a bone screw  
15 between the circular openings 62a and 62b. The narrow slots 64 allow for controlled flexing of the plate member 12B. The slots may also be beneficial in assisting the surgeon to stabilise the plate during implantation because an instrument may be inserted into the openings to hold the plate in position and, by keying into one or  
20 more of the narrow slots, the torsional movement of the plate may be controlled. Also, where the circular openings are set relatively close together and are wider in a plane located between the upper and lower surfaces of the plate than at the upper and lower surfaces, the plate may be easier to manufacture when adjacent  
25 holes are connected by a narrow slot.

The connected circular openings 62 can be in groupings of two circular openings, three circular openings or four circular openings as illustrated in FIGS. 14-16. The groupings of circular  
30 openings 62 on the plate member 12B can be in any combination of the groupings of two, three or four circular openings 62. An example of the various combinations on plate member 12B is

illustrated in FIGS 14-16. Each grouping of circular openings 62 is no less than 1.5 millimeters apart from the next grouping of circular openings 62. Each of the plurality of openings 62 has the same configuration as the openings 24, 26. All other aspects of plate member 12B are the same as plate member 12.

The bone screw 14 (FIG. 7) has an elongated shank 36, a lower tip 37, and an enlarged upper portion 40 affixed to one end of the shank 36. The lower tip 37 of the bone screw 14 communicates with a helical thread 38 that begins at the lower tip 37 and terminates at the upper portion 40. The enlarged upper portion 40 has a generally ellipsoid-shaped outer surface 41, a generally cylindrical central bore 42 and upper walls 43. The upper walls 43 of the enlarged portion 40 have at least 2 radial slits 44 intersecting the bore 42, and in a preferred embodiment, four radial slits 44 intersecting the bore 42, as seen in FIG. 9. The central bore 42 includes internal threading 46 on a portion of the cylindrical surface 45, as illustrated in FIGS. 7 and 10. The ellipsoid-shaped surface 41 of the upper portion 40 interfaces with the cavities 30 of the openings 24, 26 and elongated slots 28 (see FIG. 10) or the plurality of circular openings 60, 62, as will be described more fully hereinafter.

A locking member 48, as shown in FIG. 8, has lower and upper portions 50, 52 respectively and a top surface 51, with the locking member 48 being sized and shaped to fit into the cylindrical central bore 42 of the bone screw 14. The locking member 48 includes external threading 54 on its lower portion 50 which engages the corresponding internal threading 46 of the central bore 42. A tool receptive socket such as hexagonal socket 56 (FIG. 9) is provided on the flat top surface 51, so that the locking member 48 can be rotated using a hexagonal wrench or other such tool or

instrument. When locking member 48 is threaded into the central bore 42 of bone screw 14, the upper walls 43 expand outwardly further enlarging the upper portion 40.

5           As shown in FIGS. 10-12, the angular shape of the cavity walls 31 allows for both transverse and longitudinal angulation of an implanted bone screw 14. The ellipsoid-shaped surface 41 allows the upper portion 40 of the bone screw 14 to be freely rotatable within the plate member cavity 30 prior to insertion of the locking member 48. After the bone screws 14 have been positioned within the openings 24, 26, slots 28 or plurality of circular openings 60, 62 of the plate members 12, 12A or 12B and implanted in the vertebrae of a patient, the locking members 48 are threaded into the central bore 42 of the bone screws 14. The threading 54 of the locking member 48 engages the threading 46 of the central bore 42 and the radial slits 44 allow the upper wall portions 43 to expand outwardly as the locking member 48 is tightened into the central bore 42 (FIG. 9).

20           When the locking member 48 is threaded into the central bore 42 of bone screw 14, the ellipsoid-shaped outer surface 41 of the upper portion 40 expands to a spherically-shaped outer surface 41a which causes the upper wall portions 43 to grip the cavity walls 31 so as to lock each bone screw 14 into a selected position within the openings 24, 26, slots 28 or plurality of circular openings 60, 62 of the plate members 12, 12A or 12B as illustrated in FIGS. 11 and 12. The geometry of the final expanded shape of the spherically-shaped outer surface 41 allows for an interference fit that provides a solid rigid mating mechanism within the conically-shaped cavities 30. The two inverted cones 31a, 31b with the matching base circles 31c of the cavities 30 provide for line contact with the spherically-shaped expanded outer surface 41 of the upper walls 43. This allows for a secure locking mechanism between the bone screw 14

and the plate member 12. This is particularly true because a spherically-shaped bone screw will deform into an ellipsoid-shape when expanded which will not engage in line contact with a spherically or conically shaped opening. The inventive locking mechanism between the plate member 12, 12A or 12B and the bone screws 14 locks the bone screws 14 into the plate member 12, 12A or 12B which prevents the implanted bone screws 14 from backing out of the plate member 12, 12A or 12B. This in turn prevents the bone screws 14 from backing out of the vertebrae. The ability of the inventive bone fixation apparatus 10 to lock the bone screws 14 into the plate member 12, 12A or 12B is critical in anterior cervical spine applications because if implanted bone screws back out of the vertebrae in this area of the spine the bone screws can cause serious injury to the patient. The present locking mechanism, plus the geometry of the plate member 12, 12A and 12B allows the bone fixation apparatus 10 to provide a rigid construct when initially implanted. However, as the implanted bone screws loosen over time, the bone fixation apparatus 10 becomes semi-rigid and provides a construct that is somewhat flexible and compliant. Further, the locking mechanism and the plate geometry allows for variable initial rigidity at the bone screw 14 and plate member 12, 12A and 12B interface. Variable rigidity of the locking mechanism means that the bone screw 14 can be locked into the plate member 12, 12A or 12B so as to provide a very rigid interface between the bone screw and the plate member in which there is no movement of the bone screw 14 within the cavity 30 or the bone screw 14 can be locked into the plate member 12, 12A or 12B so as to provide a less rigid interface between the bone screw and the plate member in which there is a small amount of movement or flexing of the bone screw 14 within the cavity 30.

During implantation, the configuration of the openings 24, 26 provides secure fixation at the ends of the plate member 12, 12A and 12B while the slots 28 and plurality of circular openings 60, 62 provide for a variation in screw placement along the longitudinal axis of the plate member 12, 12A and 12B. The bone fixation apparatus 10 can be sized to be used on cervical or lumbar vertebrae in either an anterior or posterior location. The bone fixation apparatus 10 can also be sized to be used on other bone surfaces in addition to vertebrae.

10

Although the present invention has been described with reference to its preferred embodiments, those skilled in the art will recognize changes which may be made in form or structure which do not part from the spirit of the invention already described in the specification and embodied in the claims which follow.

15

**CLAIMS**

1. A bone fixation apparatus, comprising:
  - a) an elongated plate member having a longitudinal  
 5 plane, a longitudinal axis, upper and lower surfaces, opposed longitudinal side edges, at least two pairs of circular openings and a plurality of circular openings positioned along the longitudinal plane of the plate member, said circular openings each having a central vertical axis;
  - 10 b) said circular openings each forming a cavity with walls extending between the upper and lower plate member surfaces with at least a plurality of said cavities having smaller diameter portions at the plate member upper and lower surfaces and a larger diameter portion therebetween, for allowing transverse and longitudinal  
 15 angulation of an implanted bone screw;
  - c) a plurality of bone screws each having a threaded first end portion adapted for implantation into a patient's bone mass and an enlarged second end portion; and
  - 20 d) a locking member that connects to the second end portion of each bone screw for expanding the second end portion so as to form an interference fit between the cavity wall of the plate member and said enlarged second end portion of the bone screw thereby to lock each bone screw into a selected position within said circular openings of the plate member.
- 25 2. The apparatus of claim 1 wherein said enlarged second end portion of said bone screws in substantially ellipsoidal, part-ellipsoidal, spherical or part-spherically shaped.
- 30 3. The apparatus of claim 1, wherein the second end portion of each bone screw has a cylindrical central bore and at least two



radial slits intersecting the bore, said central bore including  
threading on a portion of a surface of the bore.

4. The apparatus of claim 2, wherein each bone screw has four  
5 radial slits intersecting the bore.

6. The apparatus of claim 2 or claim 3 wherein the locking  
member is sized and shaped to fit into the central bore of each bone  
screw and has threading on a portion of a surface of the locking  
10 member for engaging the threading on the surface of the bore.

6. The apparatus of any preceding claim, wherein said plate  
member has a transverse plane and is formed so as to include a  
curve in the transverse plane.

15

7. The apparatus of any of the preceding claims, wherein said  
plate member is formed so as to include a curve in the longitudinal  
plane of the plate member.

20 8. The apparatus of any of the preceding claims, wherein the  
plate member has a first end, a second end and a center portion  
wherein the width of the plate member is smaller in the region of the  
center portion than at the first and second ends.

25 9. The apparatus of claim 7, wherein one pair of circular  
openings is positioned at or near the first end of the plate and the  
second pair of circular openings is positioned at or near the second  
end of the plate.

30 10. The apparatus of any of the preceding claims, wherein at  
least some of the plurality of circular openings positioned along the

longitudinal plane of the plate member are spaced at least about 1.8 to 2.0 millimeters apart from each other.

11. The apparatus of claim 10, wherein the plurality of openings  
5 includes a series of at least two spaced apart circular openings.

12. The apparatus of any of the preceding claims, wherein at  
least two of the plurality of circular openings positioned along the  
longitudinal plane of the plate are connected by a narrow slot.  
10

13. The apparatus of claim 12, wherein the plurality of circular  
openings includes at least one grouping of two circular openings  
connected to each other by the narrow slot.

14. The apparatus of claim 12, wherein the plurality of circular  
openings includes at least one grouping of three circular openings,  
connected in series by the narrow slot.  
15

15. The apparatus of claim 12, wherein the plurality of circular  
openings includes at least one grouping of four circular openings  
connected in series by the narrow slot.  
20

16. The apparatus of claim 12, wherein the plurality of openings  
includes any combination of series of two, three or four openings  
being connected to each other in series by a narrow slot.  
25

17. The apparatus of any of the preceding claims wherein at  
least one of the circular openings allows for transverse angulation of  
each of the bone screws of up to about 35° in each direction from  
the central vertical axis of the circular openings when a bone screw  
is inserted into said circular opening.  
30

18. The apparatus of any of the preceding claims wherein at least one of said circular openings allows for longitudinal angulation of a bone screw from about 0° to about 35° in each direction from the central vertical axis of the said at least one opening when said bone screw is inserted into the said at least one opening.
19. The apparatus of any of the preceding claims, wherein at least one of the circular openings includes a bevelled surface on the upper and/or lower surfaces of the plate member.
20. An apparatus as claimed in any preceding claim, wherein a plurality of said cavities are configured in the shape of two inverted cones with matching base circles to allow transverse and longitudinal angulation of an implanted bone screw.
21. The apparatus of any of the preceding claims, wherein the plate member is sized to be placed on adjoining cervical vertebrae.
22. The apparatus of any of claims 1-20, wherein the plate member is sized to be placed on adjoining lumbar vertebrae.
23. The apparatus of claim 21, wherein the plate member is sized to be placed on an anterior side of the cervical vertebrae.
24. An apparatus as claimed in any of the preceding claims, wherein said enlarged second end of said bone screw grips the cavity walls of said circular openings when expanded by said locking member, to lock said bone screw into a selected position within said opening.

25. The apparatus of any preceding claim, wherein the interference fit between the expanded second end portion of each bone screw and the cavity wall of the selected circular opening or selected series of openings of the plate member creates a locking mechanism that allows for variable rigidity of the locking mechanism at each bone screw and plate member interface.

26. A bone fixation plate adapted for use in a bone fixation apparatus,

10 a) having a longitudinal plane, a longitudinal axis, upper and lower surfaces, opposed longitudinal side edges, at least two pairs of circular openings and a plurality of generally circular openings positioned along the longitudinal plane of the plate member, said circular openings each having a central vertical axis;

15 b) said circular openings each forming a cavity with walls extending between the upper and lower plate member surfaces with at least a plurality of said cavities having smaller diameter portions at the plate member upper and lower surfaces and a larger diameter portion therebetween, for allowing transverse and longitudinal angulation of an implanted bone screw;

c) said plate member having a first end, a second end and a center portion wherein the width of the plate is smaller in the region of the center portion than at the first and second ends; and

25 d) said one pair of circular openings being positioned at the first end of the plate member and the second pair of circular openings being positioned at the second end of the plate member.

27. The bone fixation plate of claim 26, wherein said plate member has a transverse plane and is formed so as to include a curve in the transverse plane.

28. The bone fixation plate of claim 26 or 27, wherein said plate member is formed so as to include a curve in the longitudinal plane of the plate member.
- 5 29. The bone fixation plate of any of claims 26-28, wherein at least some of the plurality of circular openings positioned along the longitudinal plane of the plate member are spaced at least about 1.8 to 2.0 mm apart from each other.
- 10 30. The bone fixation plate of any of claims 25-29, wherein the plurality of circular openings includes a series of at least four spaced apart circular openings.
31. The bone fixation plate any of claims 26-30 wherein at least  
15 two of the plurality of circular openings positioned along the longitudinal plane of the plate with each circular opening are connected by a narrow slot.
32. The bone fixation plate of claim 31, wherein the plurality of  
20 circular openings includes a grouping of two circular openings being connected to each other by the narrow slot.
33. The bone fixation plate of claim 31, wherein the plurality of  
25 circular openings includes a grouping of three circular openings, each circular opening being connected to the next circular opening by the narrow slot.
34. The bone fixation plate of claim 31, wherein the plurality of  
30 circular openings includes a grouping of four circular openings, each circular opening being connected to the next circular opening by the narrow slot.

35. The bone fixation plate of claim 31, wherein the series of openings includes any combination from the group consisting of two circular openings being connected to each other by the narrow slot; three circular openings, each circular opening being connected to the next circular opening by the narrow slot; and four circular openings, each circular opening being connected to the next circular opening by the narrow slot.
36. The bone fixation plate of any of claims 26-35, wherein the circular openings allow for transverse angulation of a bone screw of up to about 35° in each direction from the central vertical axis of the circular openings when said bone screw is inserted into a circular opening.
37. The bone fixation plate of any of claims 26-36, wherein the circular openings allow for longitudinal angulation of a bone screw of up to about 35° in each direction from the central vertical axis of the circular openings when a bone screw is inserted into said circular opening.
38. The bone fixation plate as claimed in any of claims 26-37, wherein the circular openings include a bevelled surface on the upper and/or lower surfaces of the plate member.
39. A bone fixation plate as claimed in any of claims 26-38 wherein a plurality of said cavities are configured in the shape of two inverted cones with matching base circles to allow transverse and longitudinal angulation of an implanted bone screw.
40. An apparatus as claimed in any of claims 1-25, further comprising at least one opening in the form of an elongate slot.

41. A bone fixation plate as claimed in any of claims 26-39,  
further comprising at least one opening in the form of an elongate  
slot.

5

10

15

20

25

30

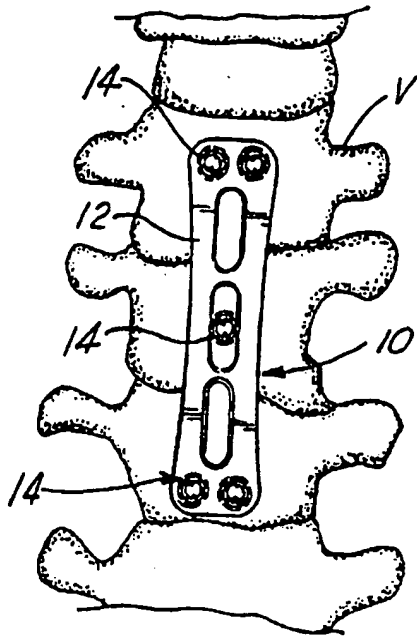


FIG. 1

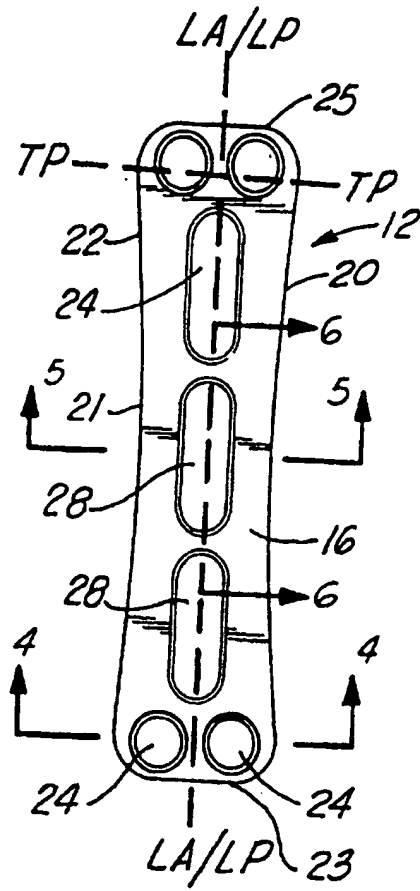


FIG. 2

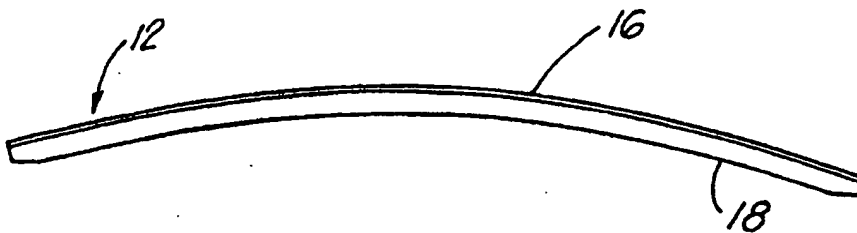


FIG. 3A

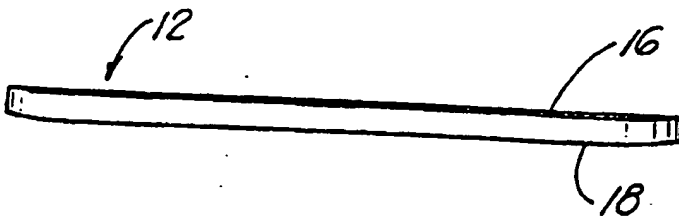
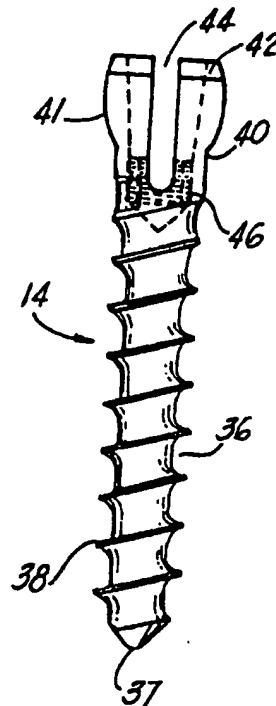
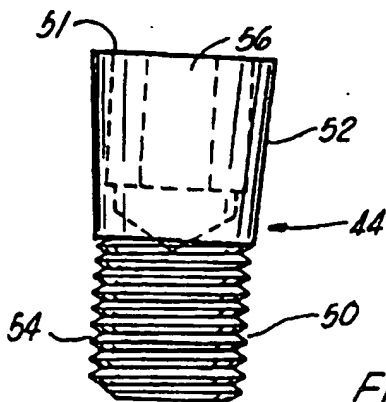
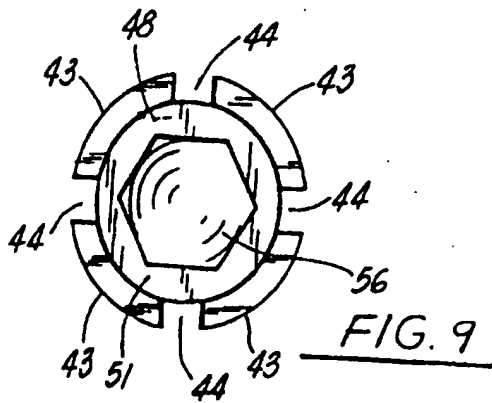
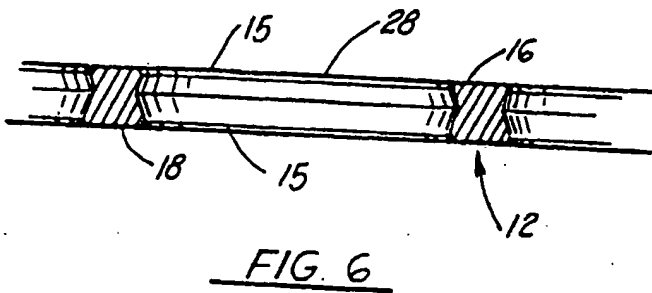
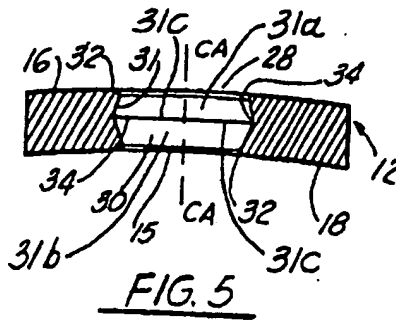
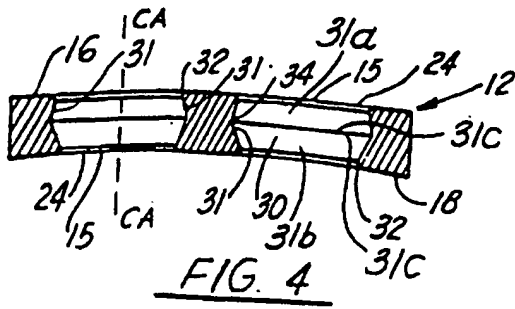


FIG. 3





3/4

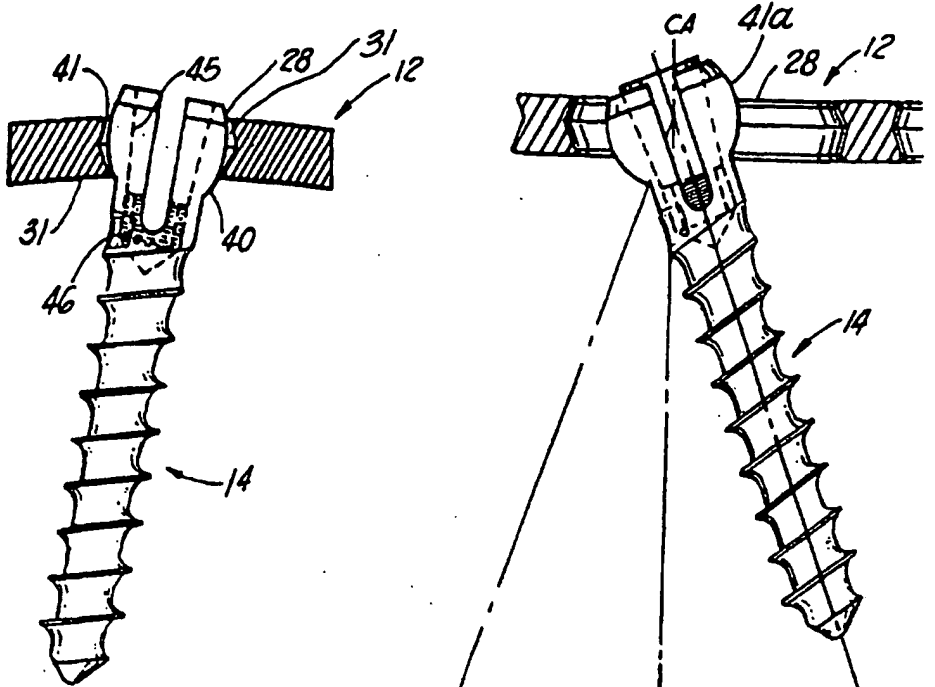


FIG. 10



FIG. 11

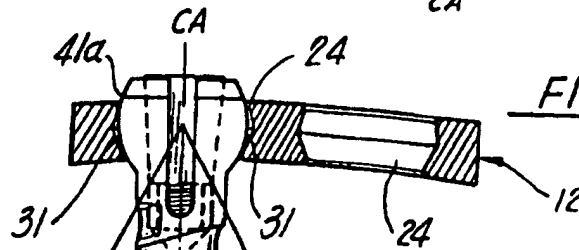
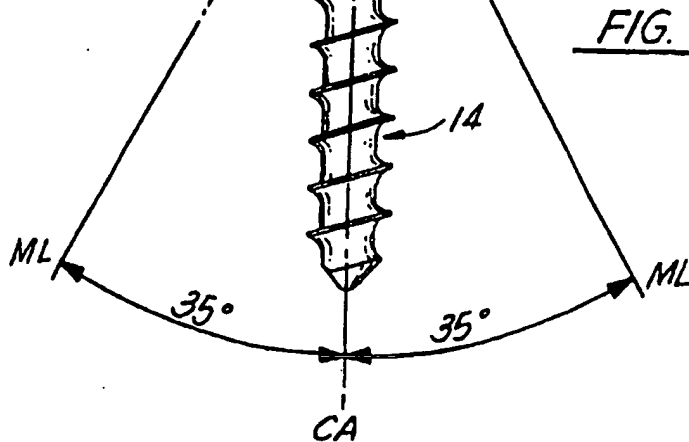


FIG. 12



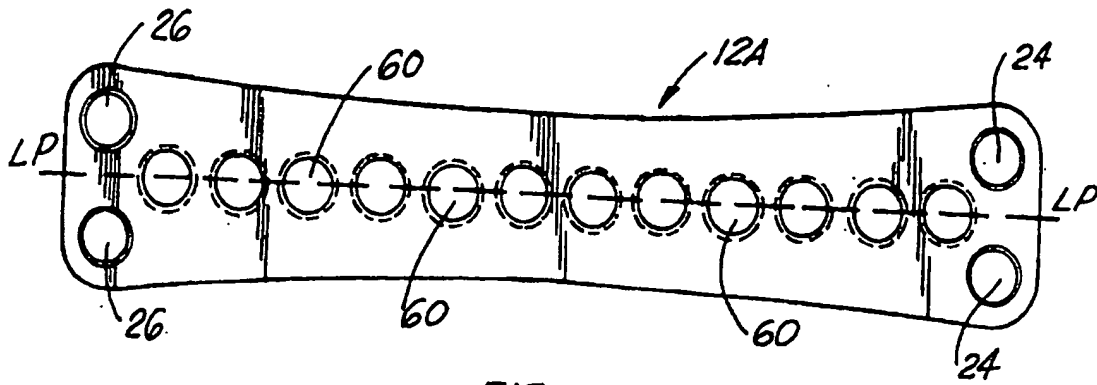


FIG. 13

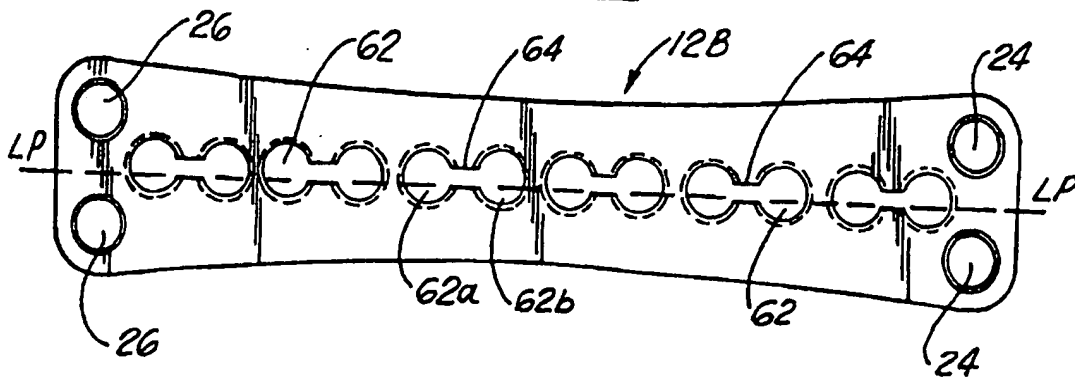


FIG. 14

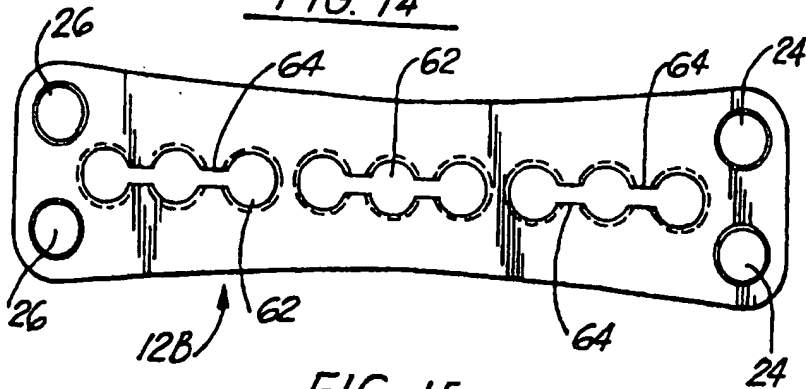


FIG. 15

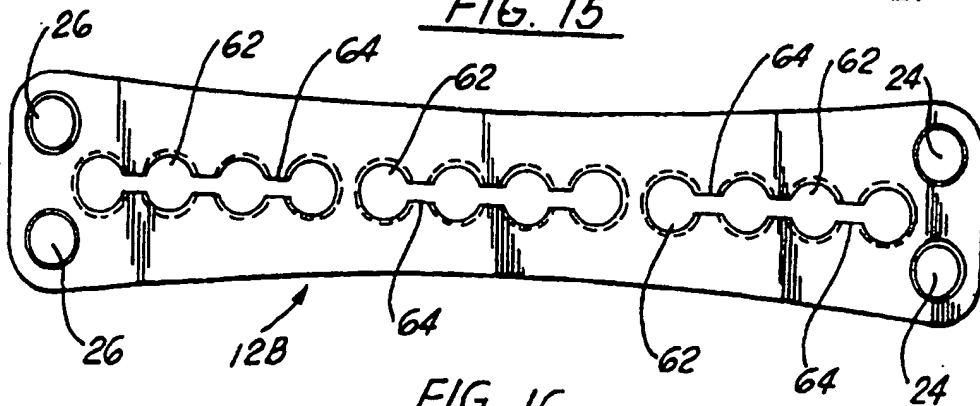


FIG. 16

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/20707

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 17/70

US CL :606/61, 69, 73

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 69-73

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
McGraw-Hill Encyclopedia of Science & Technology, 7th Edition, 1992, for definition of an ellipsoid.

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

search terms: bone plate, flexible, slot, hole, opening

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 88/03781 A (RAVEH) 06 June 1988, Figs. 1, 5-7, 15 and 25-27.	1-5
Y	US 5,364,399 A (LOWERY et al) 15 November 1994, Figs. 1-4, 8 and 9.	26-28
A	US 4,484,570 A (SUTTER et al) 27 November 1984, Figs. 2-5. and 17.	1-5, 26-28



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	
*A* document defining the general state of the art which is not considered to be of particular relevance	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to undermind the principle or theory underlying the invention.
*B* earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combinations being obvious to a person skilled in the art
*O* documents referring to an oral disclosure, use, exhibition or other means	
*P* documents published prior to the international filing date but later than the priority date claimed	*Z* document member of the same patent family

Date of the actual completion of the international search

07 MARCH 1997

Date of mailing of the international search report

25 MAR 1997

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 295-2500

Authorized officer

DAVID O. REIP

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/20707

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 6-25 and 29-41  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**